UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,388	02/10/2004	Jonathan Gressel	27084	1970

7590 08/01/2007

Martin D. Moynihan
PRTSI, Inc.
P. O. Box 16446
Arlington, VA 22215

EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
08/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,388	GRESSEL ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *9-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 17-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 2/10/04 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/889,737

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Response

Applicant's amendment of 01 May 2007 has overcome the anticipation rejections over COLD SPRING HARBOR and Wang et al, as set forth on pages 9-10 of the last Office action. Since the prior art teaches the obtention of seedless corn and Arabidopsis, wherein the seeds are the harvested portion of these crops, the prior art cannot be said to teach a trait which is not detrimental to these crop species.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification Objections

The specification remains objected to for its omission of the abandoned status of the parent application, as stated on page 2 of the last Office action.

Claim Objections

Amended claim 1 is objected to for its inclusion of errors. Errors appear in lines 6-7 in the recitation of "genetically engineered, trait, and at least one, mitigating genetic trait". The commas after "engineered" and "one" should be deleted.

Written Description

Claims 1-8 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated for claims 1-8 on pages 2-4 of the last Office action.

Applicant's arguments filed 01 May 2007 have been fully considered but they are not persuasive. Applicant urges that the specification provides sources for a variety of genes which may confer advantageous or mitigating traits.

The Examiner maintains that the specification has not demonstrated the truly benign nature of the mitigating traits on cultivated crops transformed therewith, as discussed below. Furthermore, the claims are not drawn merely to the introduction of particular coding sequences. Instead, the claims are broadly drawn to transforming a crop plant with a multitude of sequences including coding sequences, antisense sequences, ribozyme-encoding sequences, etc. which somehow confer the advantageous or mitigating traits. No guidance is presented in the specification for these multitude of sequences or any conserved sequence domains therein, which conserved domains are responsible for conferring the advantageous or mitigating trait.

Enablement

Claims 1-8 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 4-8 of the last Office action for claims 1-8.

Applicant's arguments filed 01 May 2007 have been fully considered but they are not persuasive. Applicant urges that the specification has provided numerous examples of crop plants transformed sequences conferring with advantageous and mitigating traits. The Examiner maintains that Applicant has only reduced to practice a few

examples of two different crop species transformed with the same type of mitigating trait gene, and that Applicant has not demonstrated that those few sequences evaluated actually were benign to crop plants.

First, the Examiner notes that Examples 3-4, drawn to transformed corn and rice plants, are prophetic. Applicant is directed to page 10 of their Response, bottom two paragraphs, where Applicant states that COLD SPRING HARBOR cited by the Examiner is deficient because it merely provides prophetic examples.

Furthermore, the Examiner notes that the transformed tobacco and Brassica plants obtained by Applicant did not have benign traits conferred by the mitigating genetic trait. Instead, both the transformed dwarf tobacco and the transformed dwarf Brassica were inefficient competitors with wild-type tobacco or Brassica (see, e.g., page 62 of the specification, bottom two paragraphs; and page 71, penultimate paragraph). Both homozygous transgenic tobacco and homozygous transgenic Brassica failed to produce flowers as well. See also page 7 of the Response, penultimate paragraph.

Since Brassica seeds are the harvested portion of the crop, this is particularly deleterious. Such competitively disadvantaged plants would not be able to grow well when planted in a field with vigorous weeds or when mixed with some non-transgenic seeds. Thus, Applicant has not provided any examples of crop plants transformed with a sequence conferring a truly mitigating yet benign trait.

Anticipation

Claims 1-3 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (US 5,948,956 filed 16 October 1997), as stated on page 10 of the last Office action.

Applicant's arguments filed 01 May 2007 have been fully considered but they are not persuasive. Applicant urges that Lee et al do not reduce to practice plants transformed with both an herbicide resistance gene and a second gene conferring a mitigating trait. Applicant further urges that the inventors of Lee et al later published an article by Reichman et al demonstrating that transgene flow had in fact occurred.

The Examiner maintains that Lee et al teach the transformation of turfgrass plants with both an herbicide resistance gene and a second gene conferring male sterility or dwarfism, as claimed. Dwarfism or male sterility would not be deleterious to turfgrass, which is not grown for its flowers (see also page 63 of the specification, lines 19-21, where it is admitted that male sterility would not be deleterious for crop plants not grown for their flowers).

See *In re Sivaramakrishnan*, 213 USPQ 441 (CCPA 1982), which teaches that the "[f]act that patentee of patent reference may not have actually reduced specific mixture to practice has no bearing on whether mixture is described in printed publication under Section 102(b)."

Regarding Reichman et al, that reference merely reports on the subset of plants taught by the patent which do not contain the second mitigating gene.

Obviousness

Claims 1-3 and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/42326 (MOGEN INTERNATIONAL) in view of Christou et al. (US 6,114,603 filed 27 March 1998), as stated on pages 11-12 of the last Office action.

Applicant's arguments filed 01 May 2007 have been fully considered but they are not persuasive. Applicant urges that MOGEN INTERNATIONAL does not teach the prevention of transgene flow or the tight genetic linkage of the genes conferring the advantageous trait and the mitigating trait.

The Examiner maintains that MOGEN INTERNATIONAL teaches a method for producing the same plants as claimed.

In response to applicant's argument that MOGEN INTERNATIONAL does not teach the prevention of transgene flow, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding the linkage of the two genes, MOGEN INTERNATIONAL does not prevent such linkage. They merely state that the two genes may be linked on the same genetic construct, *or* that they may be introduced simulataneously on separate genetic constructs. Note also that Applicant's definition of "tightly linked" is broad and circular, merely stating that the result of such linkage would be the introgression of both traits into an uncultivated interbreeding species. Such introgression could occur whether the

two genes were introduced on the same genetic construct, or on separate genetic constructs which were integrated into the same region of the plant genome.

Claims 1-3 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/30162 (FORBIO RESEARCH) in view of Boudet et al (US 5,451,514), as stated on pages 12-13 of the last Office action.

Applicant's arguments filed 01 May 2007 have been fully considered but they are not persuasive. Applicant urges that the male sterility taught by FORBIO is not benign to cultivated crop plants, and that the combination of references fails to teach the prevention of trangsene flow.

The Examiner maintains that male sterility in tree plants not harvested for their flowers indeed constitutes a benign trait, as admitted by Applicant on page 63 of the specification, lines 19-21.

Regarding the explicit teaching or suggestion of trangsene flow prevention, see *Ex parte Obiaya* cited above.

Conclusion

Claims 4-6 and 17-18 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest isolated genes conferring the particularly claimed mitigating traits or crop plant transformation therewith (in combination with the particularly claimed advantageous traits), as stated for claims 5-6 on page 13 of the last Office action.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 28, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638